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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/829,558    03/28/97    MERUELO    D    8105-009

HM12/0720

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EXAMINER

ZEMAN, R

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

16  
07/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Advisory Action

Application No.  
08/829,558

Applicant(s)  
Meruelo et al

Examiner  
Robert A. Zeman

Art Unit  
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jun 22, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Jun 22, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☒ they raise the issue of new matter. (See NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: see attached.

4. ☒ Applicant's reply has overcome the following rejection(s):  
see attached.
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
it is not directed solely to the issues raised by the Examiner in the final rejection.
7. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 1-10, 18-23, and 27-31
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other:

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### ADVISORY ACTION

- The proposed amendment to claims 1 and 18 contain the limitation “said chimeric envelope protein causes ablation of endogenous viral tropism. Applicant states that support for said amendment can be found on page 6, lines 22-23 of the specification, as filed. Said passage merely states that “it is **desirable** to alter the tropism of the Sindbis virus vectors....” and hence does not constitute support for the proposed amendment. Consequently, the proposed limitation raises the issue of **new matter**. Additionally, the cited passage refers only to sindbis virus vectors while the proposed claims are drawn to all virus vectors.
- The rejection of claims 1-6, 18-23 and 27-31 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the insertion of the particular “ZZ” IgG binding domain of Protein A into a viral vector, does not reasonably provide enablement for any other IgG binding domain of Protein A is maintained for reasons of record. Applicant argues that the IgG binding domains are known and that Protein A contains 5 homologous IgG binding domains that are functionally interchangeable. Applicant further argues that the a sindbis virus vector using an unrelated molecular construct successfully made demonstrating that domains/genes other than the ZZ domain can be used in the sindbis vector. Applicants arguments have been fully considered and are deemed to be non-persuasive. Applicant’s argument regarding the interchangeable use and homology of

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binding domains E, D, A, B, C and Z is valid. However, the rejected claims are drawn to **all** viral vectors not just the sindbis virus. Consequently, the rejection of claims 7-10 is withdrawn in light of Applicant's arguments. The rejection of claims 1-6, 18-23 and 27-31 is maintained.

- The rejection of claims 1-10, 18-23, and 27-31 under 35 U.S.C. 103(a) as being unpatentable over Barber et al. (US Patent 5,591,624) and Wickham et al. (US Patent 5,846,782), in view of Nilsson et al. (Nilsson et al. 1987 Protein Eng. 1: 107-113) is maintained for reasons of record. Applicant's arguments are based on limitations not found in the claims. Applicant's arguments are based on the limitation "ablation of endogenous viral tropism". The amendment was not entered since it raised new issues. Consequently, any arguments that rely on the amended material are based on limitations not found in the claims.
- The 37 CFR 1.132 Declaration filed on 6-22-2001 will not be considered because good and sufficient reasons why it was not earlier presented have not been shown. Said Declaration should have been presented in response of the Office Action mailed 4-12-2000 (Paper No. 4).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

  
DONNA WORTMAN  
PRIMARY EXAMINER

Robert A. Zeman

July 19, 2001